



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,120	12/30/2003	Richard Boyd	NOR-015CP2 and 286336.154	3284
23483	7590	02/21/2008	EXAMINER	
WILMERHALE/BOSTON				
60 STATE STREET				
BOSTON, MA 02109				
			ART UNIT	PAPER NUMBER
			1644	
			NOTIFICATION DATE	DELIVERY MODE
			02/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

michael.mathewson@wilmerhale.com

teresa.carvalho@wilmerhale.com

sharon.mathews@wilmerhale.com

Office Action Summary

Application No.

10/749,120

Applicant(s)

BOYD ET AL.

Examiner

David A. Saunders

Art Unit

1644

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-57, 61-64, 66-84, 89, 90, 92 and 94-100 is/are pending in the application.
- 4a) Of the above claim(s) 43, 61-64, 66-84, 90, 92 and 94-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-42, 44-57, 89, 99 and 100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Art Unit: 1644

AMENDMENT ENTRY

Amendment of 11/16/07 has been entered. Claims 38-57, 61-64, 66-84, 89-90, 92, 94-100 are pending. Claims 38-42, 44-57, 89 and 99-100 are under examination.

CORRECTIONS REGARDING PREVIOUS OFFICE ACTION

The following corrections pertain to the previous Office action:

At page(s) 6, line 1 "8/11/05" should have read as --8/11/04--.

OBJECTION(S)/REJECTION(S) OF RECORD WITHDRAWN

The amendment has overcome previously stated issues as follows:

The objection to claim(s) 46-48 and 100.

The rejection of claim(s) 38 and 89 under 35 USC 112, 2nd paragraph.

The rejection of claim(s) 57 under 35 USC 112, 1st paragraph. The examiner concurs that para [0217] of applicant's disclosure, as printed in US 2005/0042679, supports claim 57.

The prior art rejection of claim(s) 38-39, 42, 44-46, 48, 50-57, 89 and 99 under 35 USC 103(a) as being unpatentable over Coy et al (5,073,624) in view of both Fabris (ref A55 cited in IDS of 8/11/04) and Mocchegiani et al (ref A150 in IDS of 8/11/04). None of these references teaches the detection of TRECs as a means of monitoring the production of new T-cells.

MAINTAINED OBJECTION(S) TO CLAIMS

Claim 45 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Applicant has amended claim 45 to be dependent from claim 44. The Office considers that "administration of a pharmaceutical" (in dependent claim 45) does not further limit "chemical castration" (in claim 44). If the "chemical" administered in the method of "chemical castration" is not a "pharmaceutical", what else is it? Applicant's

response of 11/16/07 (page 12) has not explained how dependent claim 45 would have less embodiments than those encompassed by base claim 44. The previous action indicated (page 4) that if one of claims 44 and 45 would have embodiments which would not be encompassed by the other, such embodiments must be specifically pointed out, and the corresponding sections of the disclosure must be specifically pointed out by page and line numbers.

NEW REJECTION(S) UNDER 35 USC 112, FIRST PARAGRAPH

Claims 38-42, 44-57, 89 and 99-100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 38 and 89 recite new matter.

Specifically the Office finds no support for measuring and comparing both the level of marker in the patient's blood or serum, and the level of newly produced T-cells by monitoring TRECs. Applicant apparently considers that the amendment of claims 38 and 89 is supported by page 58, lines 1-3, which recite "By following the concentration of any one, or any combination, of these markers..." and by page 64, lines 10-15, which teach "following the markers" (e.g. Ki67 etc. of proliferating T-cells) "as well as by TREC analysis". Applicant apparently considers that the recitations of "markers" at these two locations are connected. The examiner considers that they are not connected for the following reasons:

First, the "markers" recited at page 58, lines 1-3, are indented under section "A" commencing at page 57, last line; and the whole context of section "A" concerns only markers found in blood or serum (e.g. page 58, lines 19-20). On the other hand, the monitoring of the level of newly produced T-cells by monitoring TRECs recited at page 64, lines 10-15, falls under section "C"; and the whole context of section "C" is that monitoring T cell production is "another method that may be used to determine activation of then thymus." The teachings therein thus specifically recite that such

Art Unit: 1644

analysis is "another method", rather than an add-on method to be conducted in conjunction with what was taught in sections "A" and "B".

Second, the "markers" recited in section "C" are not functional equivalents of the "markers" recited in section "A", since the former are markers within or on cells, while the latter are "markers" secreted by cells. Thus recitation of "any one, or any combination, of these markers..." in section "A" is not inclusive of the cellular "markers" recited in section "C".

Thirdly, in applicant's hodge-podge collection examples, one finds no single example wherein the thymic reconstitution of one group of animals was monitored by means of determining both the level of a marker in the patient's blood or serum, and the level of newly produced T-cells by monitoring TRECs.

ART OF INTEREST

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haynes et al (US 6,544,747, cited on Form 892) show TREC analysis, as a way of measuring thymopoiesis in immune reconstitution strategies. They do not suggest that TREC analysis be conducted in conjunction with the analysis of other markers.

FINALITY

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1644

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 61-64, 66-84, 90, 92 and 94-98, which are not of Group I, and which are thus drawn to invention(s) nonelected with traverse in the reply filed on 4/10/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 2/13/08 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644

